K020067

510(k) Summary of Safety and Effectiveness

Gyrus ENT Somnoplasty Generator

Submitted by:

Gyrus ENT
2925 Appling Rd.
Bartlett, TN 38133

Contact Person:

Jeffrey W. Cobb
Vice President Regulatory Affairs

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Date Summary Prepared:

January 7, 2002

Name of the Device:

Proprietary Name: Gyrus ENT Somnoplasty Generator

Proprietary Name: COGENT 1

Common/Usual Name: Electrosurgical Generator and Accessories

Classification Name: Electrosurgical Device (per 21 CFR 878.4400)

Predicate Device:

Somnus Model S1 (K000501)

Description:

The Gyrus ENT Somnoplasty Generator has controls for maximum temperature, energy delivered and time of energy delivery. The unit has readouts for total energy delivered, impedance, and temperature for two thermocouples. Connectors on the front panel include connector for active electrode and dispersive electrode. The foot pedal is connected on the back panel.

Accessories included with the generator are a power cable and a footswitch.

Statement of Intended Use:

The Gyrus ENT Somnoplasty Generator, in combination with Gyrus ENT Somnoplasty Electrodes, is intended for use in the coagulation of soft tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Devices:

The Gyrus ENT Somnoplasty Generator has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance validation testing has been done to validate the performance of the device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jeffrey W. Cobb
Vice President Regulatory Affairs
Gyrus ENT
2925 Appling Road
Bartlett, TN 38133

APR - 4 2002

Re: K020067
Trade/Device Name: Gyrus ENT Somnoplasty Generator
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 8, 2002
Received: January 9, 2002

Dear Mr. Cobb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Yet Assigned~~ K020067

Device Name: Gyrus ENT Somnoplasty Generator
ELECTROSURGICAL GENERATOR

Indications For Use: The Gyrus ENT Somnoplasty Generator with the Gyrus ENT Soft Tissue Coagulating Electrodes is indicated for the coagulation of soft tissue.

The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications for Use: The use of the Gyrus ENT Somnoplasty Generator is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interests of the patient.

Somnoplasty may be contraindicated in patients with a compromised immune system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional Format
1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020067